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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,690	06/23/2003	Laszlo Revesz	4-31180B	9514

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NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/601,690

**Applicant(s)**

REVESZ, LASZLO

**Examiner**

Deepak Rao

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-9 ~~6~~/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9 ~~6~~/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/111,233.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>091703</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

Claims 6-9 are pending in this application.

#### *Specification*

The title of the invention is not descriptive of the instantly claimed subject matter. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested:

IMIDAZO[4,5-B]PYRIDINE COMPOUNDS AND THEIR PHARMACEUTICAL USE

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. The claims recite "A compound.... **and** all pharmaceutically-acceptable and -cleavable esters thereof **and** acid addition salts thereof". This is confusing because it is not clear if a compound **or** the salt, etc. is claimed or a mixture of the compound and the salt is claimed. Replacing the term "and" (both occurrences) with -- or -- is suggested.
2. Claim 6, last line, the term "sales" appears to be a typographical error for -- salts --.

3. Recitation of the term “cleavable esters” in the instant claims is deemed as indefinite.

This term is explained in the specification at page 17, last paragraph and it is stated that these are “preferably prodrug ester derivatives, such being convertible by solvolysis or cleavage under physiological conditions to the corresponding Agents of the Invention which comprise free hydroxyl groups”. In that sense recitation of ‘cleavable ester’ is acceptable. However, the definition of various substituent groups in the formula already include such groups, i.e., acids as well as esters (see e.g., the definition of  $R_{12}$  which includes “carboxylate or thiocarboxylate optionally in the form of .... ester”). Therefore, it is not clear what is the difference between these substituent groups and the ‘cleavable ester which is converted from the free acid’ of the claims. In addition, it is not clear whether compounds already bearing an ‘ester’ group are excluded from being a potential “cleavable esters”. If compounds bearing these groups, which are likely to undergo *in vivo* transformation, are excluded then what is included in the definition of ‘cleavable ester’ and where on the compound of formula (I), these groups are placed, is not clear. Since both the free acid form as well as the esters thereof of the compounds of formula V are already included in the claim, deletion of the term ‘cleavable esters’ from the claims is suggested.

4. In claim 7, in the definition of  $R_{13}$ , there is a term “ $CH_2NR_{15}R_{16}$ ” (see page 5, line 7), however, there is no definition provided for variables  $R_{15}$  and  $R_{16}$ .
5. In claim 7, in the definition of  $R_{13}$ , the term “ $-CH_2CH_2R_{15}R_{16}$ ” (see page 5, line 7) is not understood. First there is no definition for the variables  $R_{15}$  and  $R_{16}$ , further, there are more than four attachments to the terminal carbon, which exceeds the available valency.

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6. In claim 7, a definition has been provided for  $R_{11}$  and  $R_{12}$  (see page 5, line 13), however, these variables do not appear anywhere in the claim. Further, the definitions are not consistent with the definition of  $R_{11}$  or  $R_{12}$  provided in claim 6.
7. Regarding claim 7, the phrase "heteroatom (e.g. O, S or N)" (see page 5, line 15) renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
8. In claim 7, in the definition of Y', the term " $-\text{CH}_2\text{CH}_3-$ " (see page 5, line 16) is not understood.
9. Claim 8 does not end with a period.
10. In claim 9, the recitation "an Agent of the Invention" in each of the steps (i) to (v) is redundant. It is suggested to replace the above phrase with -- a compound --.
11. Claim 9 is an independent claim and does not provide the structural formula V and the definitions for many of the variables that are present in the structural formulae. The claim recites that the variables "are as previously defined", however, does not refer specifically to any of the claims.

***Allowable Subject Matter***

Claims 6-9 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. The references of record do not teach or fairly suggest the instantly claimed compounds, see e.g., US 5,739,143.

Receipt is acknowledged of the Information Disclosure Statement filed on September 17, 2003 and a copy is enclosed herewith.

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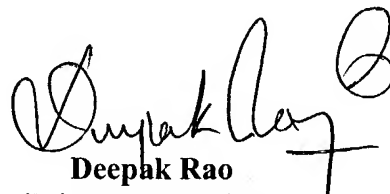
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

September 30, 2004